# Transfusion Related Acute Lung Injury (TRALI) Risk Mitigation Policy

**PURPOSE**:

This policy outlines the Blood Bank of Delmarva's (BBD's) approach to TRALI risk reduction measures.

**PRINCIPLE**:

In order to reduce the risk of TRALI to the patient's we serve, BBD will adhere to 30th edition of the *Standards for Blood Banks and Transfusion Services (BBTS Standards)* 5.4.1.3, 'Plasma, Apheresis Platelets, and Whole Blood for allogeneic transfusion shall be from males, females who have not been pregnant or females who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies'.

'For apheresis platelet components, standard 5.4.1.3 shall be implemented by October 1, 2016' (*BBTS Standards* 5.4.1.3.1).

HLA antibody screening addresses only the risk of TRALI from HLA antibodies (*AABB Technical Manual, 18th edition*).

**RESPONSIBILITIES**:

Executive Management (EM) is responsible for providing sufficient time for SOP development, validation and staff training in applicable SOPs.

Operations Team (OT) is responsible for ensuring the policy/procedure complies with applicable regulations, manufacturer's current package inserts and/or operator manuals and that staff are trained in the policy and procedure.

Personnel writing (Technical Writers) SOPs and/or Policies are responsible for ensuring the entire procedure is periodically reviewed and needed changes and/or enhancements are made before the annual review date.

Critical Operations Department Staff are responsible for ensuring that critical SOPs and Policies are followed and reporting any deviations or failures to appropriate management.

All Employees are responsible for understanding the quality policy and objectives. All employees are responsible for the quality of their work and for ensuring that work is performed to the applicable standard, regulations and written procedures. All employees have the responsibility and authority to stop any work in process, in the event any product, supply or operation is suspected to be nonconforming.

**RELATED DOCUMENTS**: N/A

**DEFINITIONS**: N/A

**EQUIPMENT**: N/A

**REAGENTS/MATERIALS/SUPPLIES/LIMITATIONS**: N/A

**QC/REPORTING RESULTS/LIMITATIONS**: N/A

**SPECIMEN PREPARATION**: N/A

**SAFETY**: N/A

**POLICY**:

I. BBD's approach to TRALI risk reduction measures apply to the following products:

A. Fresh Frozen Plasma (FFP), Fresh Whole Blood (FWB) or Apheresis Platelets

B. Whole blood

II. BBD's TRALI risk reduction measures include collecting products addressed in Step I. of this procedure from the following donors:

A. Male donors

B. Females who have never been pregnant

C. Females who have been tested and found to be HLA antibody negative since their last pregnancy

III. Measures to accomplish TRALI risk reduction include but are not limited to:

A. Identifying female donors with any history of pregnancy during the donation eligibility process, which includes identifying females who had a subsequent pregnancy after a negative HLA antibody test.

B. Testing for HLA antibodies in targeted female donor populations with a pregnancy history (e.g., AB donors, plateletpheresis donors and FWB donors), and retesting females who had a subsequent pregnancy following a negative HLA antibody test.

C. Refraining from distributing fresh whole blood, platelet, or plasma products for transfusion purposes, if collected from female donors with a history of pregnancy and an unknown or positive HLA antibody status.

D. Donors implicated in a TRALI event or associated with multiple events of TRALI shall be evaluated regarding their continued eligibility to donate.

**ADDITIONAL INFORMATION**:

Exception to this policy may be made with Medical Director and treating physician's approval.

**REFERENCES**:

Technical Manual, Bethesda, MD: AABB, 18th edition, 2014

Standards for Blood Banks and Transfusion Services, Bethesda, MD: AABB, 30th edition, 2016.

AABB Association Bulletin #14-02 TRALI Risk Mitigation for Plasma and Whole Blood for Allogeneic Transfusion, January 29, 2014.